PMA Final Decisions for March 2011

U.S. Food & Drug Administration

Below are Premarket Approvals (PMA), Product Development Protocols (PDP), Supplement and Notice Decisions. This list is generated on a monthly basis.

A PDF document that contains the "Approval letter and Summary of Safety and Effectiveness" is being added to this listing for each PMA. The PMA number will appear as a link if this document is available.

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
P080020 **[1]** **3/22/11**	Gel-One	Seikagaku Corporation Tokyo, Japan 100-0005	Approval for the Gel-One™. The device is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to non-pharmacologic therapy, non-steroidal anti-inflammatory drugs (NSAIDs) or analgesics, e.g., acetaminophen.
P080025 **[2]** **3/14/11**	Medtronic® InterStim® Therapy System	Medtronic Neuromodulation Minneapolis, MN 55432	Approval for the Medtronic® InterStim® Therapy System. The device is indicated for the treatment of chronic fecal incontinence in patients who have failed or could not tolerate more conservative treatments.
APPLICATION NUMBER / DATE of APPROVAL	**DEVICE TRADE NAME**	**COMPANY NAME CITY, STATE, & ZIP**	**DEVICE DESCRIPTION / INDICATIONS**
N18033/S048	VISTAKON	Johnson & Johnson	Approval to

3/10/11 **135-Day**	(etafilconA) Contact Lens	Vision Care, Inc. Jacksonville, FL 32256	implement an alternate method for re-sampling lenses.
P830055/S115 **3/11/11** **135-Day**	LCS Complete Total Knee System	DePuy Orthopaedics, Inc. Warsaw, IN 46581	Approval for: 1) automating all milling/grinding processes that were previously manual; 2) use of an oil-based coolant during milling/ grinding; and 3) including a new process – manual in-process clean (IPC) to remove the oil-based coolant after milling.
P840001/S102 **3/15/11** **Real-Time**	Restore Implantable Neurostimulators	Medtronic Neurological Minneapolis, MN 55432	Approval for minor firmware change.
P850007/S031 **3/11/11** **Real-Time**	Spinal-Stim	Orthofix, Inc. Lewisville, TX 75056	Approval for design modifications to the garment covering, the treatment coils, liquid crystal display, control unit housing profile, orientation of the controls, software/ firmware, power supply cord, and labeling. The device, as modified, will be marketed under the trade name Spinal-Stim and is indicated as a spinal fusion adjunct to increase the probability of fusion success and as a non-operative treatment for salvage of failed spinal fusion, where

			a minimum of nine months has elapsed since the last surgery.
P860004/S138 **3/3/11** **135-Day**	SynchroMed II Infusion System	Medtronic Neuromodulation Minneapolis, MN 55432	Approval of the following manufacturing process changes related to the Baseline test of the Implantable SynchroMed II Infusion Pump, Model 8637: 1) automation of the transfer of baseline test data; 2) change the duty cycle and lower the specification limit of the dynamic current test; and 3) an increase to the time to measure the micro awake current.
P860019/S264 **3/31/11** **135-Day**	Apex Monorail and Apex Over-the-Wire PTCA Dilation Catheter/Maverick 2 Monorail PTCA Catheter/Maverick Over-the-Wire PTCA Catheter/Maverick	Boston Scientific Corporation Maple Grove, MN 55311	Approval for a change to the sterilization equipment.
P880006/S067 **3/4/11** **180-Day**	Merlin Patient Care System	St. Jude Medical Sylmar, CA 91342	Approval for the Model 3330 Version 11.1 Software for the Model 3650 Merlin Patient Care System.
P880086/S189 **3/4/11** **180-Day**	Merlin Patient Care System	St. Jude Medical Sylmar, CA 91342	Approval for the Model 3330 Version 11.1 Software for the Model 3650 Merlin Patient Care System.
P890003/S177 **3/25/11**	Carelink Monitor and CardioSight®	Medtronic, Inc. Mounds View, MN	Approval for Protecta™ XT CRT-D

180-Day	Reader	55112	D314TRG and Protecta™ CRT-D D334TRG Implantable Cardioverter Defibrillators with Cardiac Resynchronization, Protecta™ XT DR D314DRG, Protecta™ XT VR D314VRG, Protecta™ DR D334DRG, and Protecta™ VR D334VRG Implantable Cardioverter Defibrillators, Model SW009 Application Software v1.0, Carelink Monitor Model 2490C upgrade, CardioSight Reader Model 2020A upgrade, and Model 2491 DDMA upgrade.
P890003/S178 3/22/11 Real-Time	Software Version SW003 (version 7.1); Relia Application Software Version SW010 (version 7.1); and Carelink DDMA Version K3 DDMA1 2v4	Medtronic, Inc. Mounds, View, MN 55112	Approval for nEw Application Software Version SW003 (version 7.1); Relia Application Software Version SW010 (version 7.1); and Carelink DDMA Version K3 DDMA1 2v4.
P890003/S189 3/22/11 180-Day	Consulta CRT-P and Syncra CRT-P Implantable Pulse Generators with Cardiac Resynchronization,	Medtronic, Inc. Mounds View, MN 55112	Approval for the Consulta CRT-P C4TR01 and Syncra CRT-P C2TR01 Implantable Pulse Generators with Cardiac Resynchronization,

			Software Model 9995 (version 7.3), CareLink Monitor Model 2490G and Model 2491 DDMA.
P890003/S192 **3/22/11** **180-Day**	Preva, Prevade and Prodigy IPGs	Medtronic, Inc. Mounds, View, MN 55112	Approval for the change of the materials, power supply, and incoming inspection process for the following AVX capacitors to be used in the above referenced IPGs. Those capacitors are: XT009, XT045, XT082, XT096, XT113, XTC002, XTC018, XTC029, XT014, XT053, XT084, XT097, XT114, XTC004, XTC019, XTC030, XT017, XT058, XT085, XT099, XT116, XTC005, XTC020, XT023, XT060, XT086, XT103, XT118, XTC006, XTC021, XT027, XT067, XT087, XT104, XT120, XTC007, XTC023, XT032, XT068, XT088, XT105, XT121, XTC008, XTC024, XT038, XT070, XT090, XT106, XT122, XTC009, XTC025, XT041, XT072, XT091, XT108, XT123, XTC010, XTC026, XT043, XT077, XT092,

			XT109, XT124, XTC013, XTC027, XT044, XT078, XT095, XT110, XTC001, XTC017, XTC028, XT097, XT118, XT009, XT017, XT044, XT070, XT085, XT087, and XT114.
P890003/S195 **3/17/11** **Real-Time**	CareLink Remote Home Monitor	Medtronic, Inc. Mounds View, MN 55112	Approval to reduce the 21-day scheduling of device interrogation requirement within the device firmware, as well as labeling modifications to disclose the effects of this programmability on the longevity of the pulse generators.
P890003/S210 **3/17/11** **Real-Time**	CareLink Home Monitor, Device and Data Management Application and CardioSight Reader	Medtronic, Inc. Mounds View, MN 55112	Approval for modifications to the CareLink Home Monitor Model 2490G, Device and Data Management Application Model 2491, and CardioSight Reader Model 2020A.
P890055/S028 **3/15/11** **180-Day**	MedStream Programmable Infusion System	Codman & Shurtleff, Inc. Raynham, MA 02767	Approval of the post-approval study protocol.
P890055/S029 **3/15/11** **180-Day**	MedStream Programmable Infusion System	Codman & Shurtleff, Inc. Raynham, MA 02767	Approval of the post-approval study protocol.
P890055/S030 **3/15/11** **180-Day**	MedStream Programmable Infusion System	Codman & Shurtleff, Inc. Raynham, MA 02767	Approval of the post-approval study protocol.

P900056/S103 **3/31/11** **135-Day**	Rotablator Rotational Angioplasty System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for a change to the sterilization equipment.
P910007/S019 **3/22/11** **180-Day**	ARCHITECT Total PSA	Abbott Laboratories Abbott Park, IL 60064	Approval for a manufacturing site located at Abbott Ireland Diagnostics Division in Sligo Ireland.
P910023/S236 **3/4/11** **180-Day**	Merlin Patient Care System	St. Jude Medical Sylmar, CA 91342	Approval for the Model 3330 Version 11.1 Software for the Model 3650 Merlin Patient Care System.
P910077/S110 **3/3/11** **Real-Time**	Latitude Patient Management System	Guidant Corporation (Boston Scientific Corporation) St. Paul, MN 55112	Approval for modification to the Latitude Patient Management System Regulated Application Software v7.0.02 on Latitude System Server (Model 6488) and Related Communicator Software Changes (Model 6476).
P920047/S044 **3/31/11** **135-Day**	Blazer II XP Cardiac Ablation Catheter/Cable/ Blazer II High Torque Distal (HTD) Ablation Catheter/Cable/ Blazer Prime	Boston Scientific Corporation Maple Grove, MN 55311	Approval for a change to the sterilization equipment.
P930016/S034 **3/4/11** **180-Day**	STAR S4 IR Excimer Laser System with Variable Spot Scanning and WaveScan WaveFront System	AMO Manufacturing USA, LLC Milpitas, CA 95035	Approval for WaveScan Wave-Front Software Version 3.68.
P950029/S056 **3/22/11** **Real-Time**	Reply/Esprit SR/DR Pacers	Ela Medical ,Inc. (Sorin Group) Plymouth, MN 55441	Approval for a new Setscrew and Torque-limiting Screwdriver

			Accessory.
P950037/S091 **3/25/11** **180-Day**	Envia, Entovis, Estella, Ecuro and Effecta Family of Pulse Generators	Biotronik, Inc. Lake Oswego, OR 97035	Approval for updated integrated circuits for use in the currently marketed Evia/ Entovis/Estella/ Ecuro/Effecta family of pulse generators.
P960011/S018 **3/8/11** **180-Day**	BVI 1% OVD Sodium Hyaluronate	Ferring Pharmaceuticals, Inc. Parsippany, NJ 07054	Approval for 1) the inclusion of directions for proper finger flange orientation in the Instructions for Use, and approval to change the trade name of the device from BD 1% OVD Sodium Hyaluronate to BVI 1% OVD Sodium Hyaluronate.
P970012/S068 **3/22/11** **180-Day**	Kappa IPGs	Medtronic, Inc. Mounds, View, MN 55112	Approval for the change of the materials, power supply, and incoming inspection process for the following AVX capacitors to be used in the above referenced IPGs. Those capacitors are: XT009, XT045, XT082, XT096, XT113, XTC002, XTC018, XTC029, XT014, XT053, XT084, XT097, XT114, XTC004, XTC019, XTC030, XT017, XT058, XT085, XT099, XT116, XTC005, XTC020, XT023,

			XT060, XT086, XT103, XT118, XTC006, XTC021, XT027, XT067, XT087, XT104, XT120, XTC007, XTC023, XT032, XT068, XT088, XT105, XT121, XTC008, XTC024, XT038, XT070, XT090, XT106, XT122, XTC009, XTC025, XT041, XT072, XT091, XT108, XT123, XTC010, XTC026, XT043, XT077, XT092, XT109, XT124, XTC013, XTC027, XT044, XT078, XT095, XT110, XTC001, XTC017, XTC028, XT097, XT118, XT009, XT017, XT044, XT070, XT085, XT087, and XT114.
P970013/S034 **3/4/11** **180-Day**	Merlin Patient Care System	St. Jude Medical Sylmar, CA 91342	Approval for the Model 3330 Version 11.1 Software for the Model 3650 Merlin Patient Care System.
P980003/S024 **3/31/11** **135-Day**	Chilli II Cooled Ablation Catheter and Cable	Boston Scientific Corporation Maple Grove, MN 55311	Approval for a change to the sterilization equipment.
P980007/S011 **3/31/11** **180-Day**	Abbott Architect Free PSA	Abbott Laboratories Abbott Park, IL 60064	Approval for a manufacturing site located at Abbott Ireland Diagnostics Division in Sligo, Ireland.
P980016/S211 **3/25/11**	Protecta™ XT DR, Protecta™ XT VR,	Medtronic, Inc. Mounds View, MN	Approval for Protecta™ XT CRT-D

180-Day	Protecta™ DR, and Protecta™ VR, Implantable Cardioverter Defibrillators; Model SW009 Application Software vi.0 Systems	55112	D314TRG and Protecta™ CRT-D D334TRG Implantable Cardioverter Defibrillators with Cardiac Resynchronization, Protecta™ XT DR D314DRG, Protecta™ XT VR D314VRG, Protecta™ DR D334DRG, and Protecta™ VR D334VRG Implantable Cardioverter Defibrillators, Model SW009 Application Software v1.0, Carelink Monitor Model 2490C upgrade, CardioSight Reader Model 2020A upgrade, and Model 2491 DDMA upgrade.
P980016/S240 **3/22/11** **180-Day**	Marquis DR/VR; Maximo DR/VR; Intrinsic 30 /Intrinsic; EnTrust; Maximo II; Virtuoso DR; Virtuoso II; Secura	Medtronic, Inc. Mounds, View, MN 55112	Approval for the change of the materials, power supply, and incoming inspection process for the following AVX capacitors to be used in the above referenced IPGs. Those capacitors are: XT009, XT045, XT082, XT096, XT113, XTC002, XTC018, XTC029, XT014, XT053, XT084, XT097, XT114, XTC004, XTC019,

			XTC030, XT017, XT058, XT085, XT099, XT116, XTC005, XTC020, XT023, XT060, XT086, XT103, XT118, XTC006, XTC021, XT027, XT067, XT087, XT104, XT120, XTC007, XTC023, XT032, XT068, XT088, XT105, XT121, XTC008, XTC024, XT038, XT070, XT090, XT106, XT122, XTC009, XTC025, XT041, XT072, XT091, XT108, XT123, XTC010, XTC026, XT043, XT077, XT092, XT109, XT124, XTC013, XTC027, XT044, XT078, XT095, XT110, XTC001, XTC017, XTC028, XT097, XT118, XT009, XT017, XT044, XT070, XT085, XT087, and XT114.
P980016/S268 3/22/11 Real-Time	Maximo II, Secura, and Virtuoso II	Medtronic, Inc. Mounds View, MN 55112	Approval for the design changes to the Multilayer Ceramic Capacitors (XC308, XC251, XC259, and XC263) for Concerto II Model D274TRK; Consulta Model D224TRK; and Maximo II Model D284TRK; Maximo II Models D284DRG, D2S4VRC; Secura

			Models D224DRG, D224VRC; and Virtuoso Models D274DRG. D274VRG; EnRhythm Model P1501DR; Vitatron DA+ C- Series Models C20A1, C20A3, C60A1, C60A3; and Vitatron DA+ T-Series Models T2OA1, T6OA1;
P980035/S147 3/22/11 Real-Time	nEw Application Software Version SW003 (version 7.1); Relia Application Software Version SW010 (version 7.1); and Carelink DDMA Version K3 DDMA1 2v4	Medtronic, Inc. Mounds, View, MN 55112	Approval for nEw Application Software Version SW003 (version 7.1); Relia Application Software Version SW010 (version 7.1); and Carelink DDMA Version K3 DDMA1 2v4.
P980035/S168 3/22/11 180-Day	Adapta; Relia; Sensia; Versa; Kappa; EnPulse; Sigma	Medtronic, Inc. Mounds, View, MN 55112	Approval for the change of the materials, power supply, and incoming inspection process for the following AVX capacitors to be used in the above referenced IPGs. Those capacitors are: XT009, XT045, XT082, XT096, XT113, XTC002, XTC018, XTC029, XT014, XT053, XT084, XT097, XT114, XTC004, XTC019, XTC030, XT017, XT058, XT085, XT099,

			XT116, XTC005, XTC020, XT023, XT060, XT086, XT103, XT118, XTC006, XTC021, XT027, XT067, XT087, XT104, XT120, XTC007, XTC023, XT032, XT068, XT088, XT105, XT121, XTC008, XTC024, XT038, XT070, XT090, XT106, XT122, XTC009, XTC025, XT041, XT072, XT091, XT108, XT123, XTC010, XTC026, XT043, XT077, XT092, XT109, XT124, XTC013, XTC027, XT044, XT078, XT095, XT110, XTC001, XTC017, XTC028, XT097, XT118, XT009, XT017, XT044, XT070, XT085, XT087, and XT114.
P980035/S197 3/22/11 Real-Time	EnRhythm	Medtronic, Inc. Mounds View, MN 55112	Approval for the design changes to the Multilayer Ceramic Capacitors (XC308, XC251, XC259, and XC263) for Concerto II Model D274TRK; Consulta Model D224TRK; and Maximo II Model D284TRK; Maximo II Models D284DRG, D2S4VRC; Secura Models D224DRG, D224VRC; and Virtuoso Models

			D274DRG. D274VRG; EnRhythm Model P1501DR; Vitatron DA+ C- Series Models C20A1, C20A3, C60A1, C60A3; and Vitatron DA+ T-Series Models T2OA1, T6OA1;
P980037/S034 3/17/11 Real-Time	AngioJet® Rheolytic™ Thrombectomy System	Medrad Interventional/ Possis Minneapolis, MN 55433	Approval for changes to the AngioJet Ultra Console software.
P990001/S068 3/22/11 180-Day	Vitatron DA+ C Series and T Series IPGs; Jade II, Topaz II, Vita IPGs	Medtronic, Inc. Mounds, View, MN 55112	Approval for the change of the materials, power supply, and incoming inspection process for the following AVX capacitors to be used in the above referenced IPGs. Those capacitors are: XT009, XT045, XT082, XT096, XT113, XTC002, XTC018, XTC029, XT014, XT053, XT084, XT097, XT114, XTC004, XTC019, XTC030, XT017, XT058, XT085, XT099, XT116, XTC005, XTC020, XT023, XT060, XT086, XT103, XT118, XTC006, XTC021, XT027, XT067, XT087, XT104, XT120, XTC007, XTC023, XT032,

			XT068, XT088, XT105, XT121, XTC008, XTC024, XT038, XT070, XT090, XT106, XT122, XTC009, XTC025, XT041, XT072, XT091, XT108, XT123, XTC010, XTC026, XT043, XT077, XT092, XT109, XT124, XTC013, XTC027, XT044, XT078, XT095, XT110, XTC001, XTC017, XTC028, XT097, XT118, XT009, XT017, XT044, XT070, XT085, XT087, and XT114.
P990001/S080 3/22/11 Real-Time	Vitatron DA+ C-Series; and Vitatron DA+T-Series	Medtronic, Inc. Mounds View, MN 55112	Approval for the design changes to the Multilayer Ceramic Capacitors (XC308, XC251, XC259, and XC263) for Concerto II Model D274TRK; Consulta Model D224TRK; and Maximo II Model D284TRK; Maximo II Models D284DRG, D2S4VRC; Secura Models D224DRG, D224VRC; and Virtuoso Models D274DRG. D274VRG; EnRhythm Model P1501DR; Vitatron DA+ C- Series Models C20A1, C20A3, C60A1, C60A3; and Vitatron DA+ T-Series

			Models T2OA1, T6OA1;
P000021/S018 **3/11/11** **180-Day**	Dimension® FPSA Flex® Reagent Cartridge	Siemens Healthcare Diagnostics, Inc. Newark, DE 19714	Approval for software changes (Version 3.1.1. to 3.3.) and associated hardware changes to the Dimension Vista® System.
P010013/S031 **3/9/11** **135-Day**	NovaSure Impedance Controlled Endometrial Ablation System	Hologic, Inc. Marlborough, MA 01752	Approval for an annealing process to the molded front grip component.
P010015/S084 **3/22/11** **180-Day**	Consulta CRT-P and Syncra CRT-P Implantable Pulse Generators with Cardiac Resynchronization, Software Model 9995 (version 7.3), CareLink Monitors	Medtronic, Inc. Mounds View, MN 55112	Approval for the Consulta CRT-P C4TR01 and Syncra CRT-P C2TR01 Implantable Pulse Generators with Cardiac Resynchronization, Software Model 9995 (version 7.3), CareLink Monitor Models 2490G and Model 2491 DDMA.
P010015/S086 **3/22/11** **180-Day**	InSync/InSync III CRT-Ps	Medtronic, Inc. Mounds, View, MN 55112	Approval for the change of the materials, power supply, and incoming inspection process for the following AVX capacitors to be used in the above referenced IPGs. Those capacitors are: XT009, XT045, XT082, XT096, XT113, XTC002, XTC018, XTC029, XT014, XT053, XT084, XT097, XT114, XTC004, XTC019, XTC030, XT017,

			XT058, XT085, XT099, XT116, XTC005, XTC020, XT023, XT060, XT086, XT103, XT118, XTC006, XTC021, XT027, XT067, XT087, XT104, XT120, XTC007, XTC023, XT032, XT068, XT088, XT105, XT121, XTC008, XTC024, XT038, XT070, XT090, XT106, XT122, XTC009, XTC025, XT041, XT072, XT091, XT108, XT123, XTC010, XTC026, XT043, XT077, XT092, XT109, XT124, XTC013, XTC027, XT044, XT078, XT095, XT110, XTC001, XTC017, XTC028, XT097, XT118, XT009, XT017, XT044, XT070, XT085, XT087, and XT114.
P010031/S171 3/25/11 180-Day	Protecta™ XT CRT-D and Protecta™ CRT-D Implantable Cardioverter Defibrillators with Cardiac Resynchronization; Model SW009 Application Software vi.0 Systems	Medtronic, Inc. Mounds View, MN 55112	Approval for Protecta™ XT CRT-D D314TRG and Protecta™ CRT-D D334TRG Implantable Cardioverter Defibrillators with Cardiac Resynchronization, Protecta™ XT DR D314DRG, Protecta™ XT VR D314VRG, Protecta™ DR

			D334DRG, and Protecta™ VR D334VRG Implantable Cardioverter Defibrillators, Model SW009 Application Software v1.0, Carelink Monitor Model 2490C upgrade, CardioSight Reader Model 2020A upgrade, and Model 2491 DDMA upgrade.
P010031/S198 **3/22/11** **180-Day**	InSync II Marquis; InSync III Marquis; InSync Sentry; InSync Maximo; Concerto; Concerto II; Consulta; Maximo II	Medtronic, Inc. Mounds, View, MN 55112	Approval for the change of the materials, power supply, and incoming inspection process for the following AVX capacitors to be used in the above referenced IPGs. Those capacitors are: XT009, XT045, XT082, XT096, XT113, XTC002, XTC018, XTC029, XT014, XT053, XT084, XT097, XT114, XTC004, XTC019, XTC030, XT017, XT058, XT085, XT099, XT116, XTC005, XTC020, XT023, XT060, XT086, XT103, XT118, XTC006, XTC021, XT027, XT067, XT087, XT104, XT120, XTC007, XTC023, XT032, XT068, XT088,

			XT105, XT121, XTC008, XTC024, XT038, XT070, XT090, XT106, XT122, XTC009, XTC025, XT041, XT072, XT091, XT108, XT123, XTC010, XTC026, XT043, XT077, XT092, XT109, XT124, XTC013, XTC027, XT044, XT078, XT095, XT110, XTC001, XTC017, XTC028, XT097, XT118, XT009, XT017, XT044, XT070, XT085, XT087, and XT114.
P010031/S222 3/22/11 Real-Time	Concerto II, Consulta, and Maximo II	Medtronic, Inc. Mounds View, MN 55112	Approval for the design changes to the Multilayer Ceramic Capacitors (XC308, XC251, XC259, and XC263) for Concerto II Model D274TRK; Consulta Model D224TRK; and Maximo II Model D284TRK; Maximo II Models D284DRG, D2S4VRC; Secura Models D224DRG, D224VRC; and Virtuoso Models D274DRG. D274VRG; EnRhythm Model P1501DR; Vitatron DA+ C- Series Models C20A1, C20A3, C60A1, C60A3; and Vitatron DA+ T-Series Models T2OA1,

			T6OA1;
P020009/S066 **3/31/11** **135-Day**	Express 2 Monorail and Over-the-Wire	Boston Scientific Corporation Maple Grove, MN 55311	Approval for a change to the sterilization equipment.
P020025/S025 **3/31/11** **135-Day**	Blazer II XP Cardiac Ablation Catheter and Cable/Blazer Prime XP Cardiac Ablation	Boston Scientific Corporation Maple Grove, MN 55311	Approval for a change to the sterilization equipment.
P020026/S081 **3/3/11** **135-Day**	CYPHER® Sirolimus-Eluting Coronary Stent, Coronary Stent on RAPTOR™ Over-the-Wire Delivery System/ RAPTORRAIL® Rapid Exchange Delivery System (Cypher Stent®)	Cordis Corporation Miami Lakes, FL 33014	Approval for automation of your stent coating process.
P020027/S013 **3/11/11** **180-Day**	Dimension® FPSA Flex® Reagent Cartridge	Siemens Healthcare Diagnostics, Inc. Newark, DE 19714	Approval for software changes (Version 3.1.1 to 3.3) and associated hardware changes to the Dimension Vista® System.
P030019/S017 **3/18/11** **135-Day**	Orthovisc®	Anika Therapeutics, Inc. Bedford, MA 01730	Approval for the sample preparation of raw material hyaluronate acid to be changed from its current formulation to a more diluted test sample.
P030025/S091 **3/31/11** **135-Day**	Taxus Express 2 Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for a change to the sterilization equipment.
P030031/S023 **3/3/11** **135-Day**	NaviStar® Thermocool® Diagnostic/Ablation Deflectable Tip Catheter	Biosense Webster, Inc. Diamond Bar, CA 91765	Approval for addition of a label during a manufacturing process step.
P030034/S005 **3/11/11** **Real-Time**	Cervical-Stim	Orthofix, Inc. Lewisville, TX 75056	Approval for design modifications to the garment covering,

			the treatment coils, liquid crystal display, control unit housing profile, orientation of the controls, software/ firmware, power supply cord, and labeling. The device, as modified, will be marketed under the trade name Cervical-Stim and is indicated as an adjunct to cervical fusion surgery in patients at high risk for non-fushion.
P030035/S070 **3/4/11** **180-Day**	Merlin Patient Care System	St. Jude Medical Sylmar, CA 91342	Approval for the Model 3330 Version 11.1 Software for the Model 3650 Merlin Patient Care System.
P030036/S004 **3/30/11** **180-Day**	SelectSecure Lead	Medtronic, Inc. Mounds View, MN 55112	Approval for improvements to the chemistry, manufacturing, and controls (CMC) and elution methods and specifications for the drug coating on SelectSecure Model 3830 leads.
P030052/S004 **3/22/11** **Special**	UroVysion Bladder Cancer Kit	Abbott Molecular, Inc. Des Plaines, IL 60018	Approval to provide the definition for the pepsin activity of the Vysis protease reagent in the UroVysion package insert.
P030053/S011 **3/17/11** **180-Day**	MemoryGel™ Silicone-filled Breast implant	Mentor Corporation Santa Barbara, CA 93111	Approval of the post-approval study protocol.
P030054/S153 **3/4/11** **180-Day**	Merlin Patient Care System	St. Jude Medical Sylmar, CA 91342	Approval for the Model 3330 Version 11.1 Software for

			the Model 3650 Merlin Patient Care System.
P040016/S063 **3/31/11** **135-Day**	Veriflex (Liberté) Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for a change to the sterilization equipment.
P040033/S020 **3/16/11** **Special**	Birmingham Hip Resurfacing (BHR) System	Smith & Nephew Orthopaedics Cordova, TN 38016	Approval for revisions to the surgical technique manual.
P040036/S016 **3/3/11** **135-Day**	NaviStar® Thermocool® Diagnostic/Ablation Deflectable Tip Catheter	Biosense Webster, Inc. Diamond Bar, CA 91765	Approval for addition of a label during a manufacturing process step.
P050007/S028 **3/24/11** **Special**	Starclose SE Vascular Closure System	Abbott Vascular Devices Redwood City, CA 94063	Approval to add adjunctive compression language to the labeling and instructions for use.
P050010/S010 **3/3/11** **135-Day**	ProDisc™-L Total Disc Replacement	Synthes Spine West Chester, PA 19380	Approval for a change from a manual deburring process to an automated brush deburring process.
P050018/S012 **3/30/11** **180-Day**	AngioSculpt® PTCA Scoring Balloon Catheter	AngioScore Fremont, CA 94538	Approval for a manufacturing site located at Sterigenics in Salt Lake City, Utah.
P050039/S005 **3/31/11** **Special**	Exactech® Novation™ Ceramic AHS® Articulation Hip System	Exactech, Inc. Gainesville, FL 32653	Approval for labeling changes which add strengthening language to the femoral stem surgical technique manuals.
P050042/S010 **3/22/11** **180-Day**	ARCHITECT Anti-HCV	Abbott Laboratories Abbott Park, IL 60064	Approval for a manufacturing site located at Abbott Ireland Diagnostics Division in Sligo, Ireland.

P050043/S004 **3/17/11** **Real-Time**	Femoral Introducer Sheath and Hemostatic Device (FISH), FISH-SP Device	Morris Innovative Bloomington, IN 47403	Approval for: 1) replacing the sewn two-piece small intestine submocosa (SIS) assembly with a single SIS piece; 2) decreasing the SIS cuff length and ribbon width; 3) modifying the SIS patch to release wire connection; and 4) changing the sheath material from a high density polyethylene (HDPE) to fluorinated ethylene propylene (FEP).
P050047/S015 **3/25/11** **Special**	Juvéderm Hyaluronate Gel Implants	Allergan Medical Goleta, CA 93117	Approval for some labeling updates to improve the safe use of the device.
P050051/S009 **3/22/11** **180-Day**	ARCHITECT AUSAB	Abbott Laboratories Abbott Park, IL 60064	Approval for a manufacturing site located at Abbott Ireland Diagnostics Division in Sligo, Ireland.
P060001/S011 **3/8/11** **180-Day**	Protégé GPS and Protégé RX Carotid Stent Systems	eV3, Inc. Plymouth, MN 55441	Approval of the post-approval study protocol.
P060004/S001 **3/28/11** **Panel-Track**	MEL 80™ Excimer Laser System	Carl Zeiss Meditec, Inc. Dublin, CA 94568	Approval for the MEL 80™ Excimer Laser System. This device uses an optical zone of 6.0 to 6.5 mm in diameter and a transition zone of 2.0 to 4.0 mm for a total ablation diameter of 10.0 mm, and is indicated for primary Laser Assisted *in situ*

			Keratomileusis (LASIK) treatments for: 1) the reduction or elimination of naturally-occurring hyperopia of less than or equal to +5.0 D with or without refractive astigmatism of > +0.5 and ≤ +3.0D, with a maximum MRSE of +5.0D; 2) in patients who are 21 years of age or older; and 3) with documentation of stable manifest refraction over the past year as demonstrated by change in sphere and cylinder of ≤ 0.5D.
P060006/S017 **3/31/11** **135-Day**	Express SD Monorail Premounted Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for a change to the sterilization equipment.
P060007/S007 **3/22/11** **180-Day**	ARCHITECT HBsAg/ Confirmatory	Abbott Laboratories Abbott Park, IL 60064	Approval for a manufacturing site located at Abbott Ireland Diagnostics Division in Sligo, Ireland.
P060008/S057 **3/1/11** **180-Day**	TAXUS® Liberté® Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for updating the Patient Guide into two separate documents (Angioplasty and Stent Education Guide and Patient Information Guide).
P060008/S060 **3/31/11** **135-Day**	Taxus Liberté Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for a change to the sterilization equipment.
P060008/S068	TAXUS Liberté®	Boston Scientific	Approval of the post-

3/11/11 **180-Day**		Corporation Maple Grove, MN 55311	approval study protocol.
P060018/S002 **3/24/11** **135-Day**	PRESTIGE® Cervical Disc	Medtronic Sofamor Danek Memphis, TN 38132	Approval for a change of location of the Orchid Anzon (formerly Anzon Company, Inc.) facility.
P060035/S006 **3/22/11** **180-Day**	ARCHITECT CORE-M	Abbott Laboratories Abbott Park, IL 60064	Approval for a manufacturing site located at Abbott Ireland Diagnostics Division in Sligo, Ireland.
P070009/S012 **3/31/11** **135-Day**	REALIZE Adjustable Gastric Band with Injection Port and Applier	Ethicon Endo-Surgery, Inc. Cincinnati, Oh 45242	Approval for the use of an alternate supplier for the injection molding of the septum and connector sleeve components of the injection port.
P070009/S013 **3/31/11** **Real-Time**	REALIZE® Adjustable Gastric Band with Injection Ports & Applier and REALIZE® Adjustable Gastric Band-C with Injection Ports & Applier and Injection Port	Ethicon Endo-Surgery, Inc. Cincinnati, OH 45242	Approval for a device change to modify the silicone material used for the Injection Port septum and Injection Port connector sleeve components, along with a minor associated labeling modification.
P070014/S020 **3/17/11** **180-Day**	LifeStent Vascular Stent Systems	Bard Peripheral Vascular, Inc. Tempe, AZ 85280	Approval of the post-approval study protocol.
P080006/S004 **3/31/11** **180-Day**	Attain Ability Straight Left Ventricular Lead	Medtronic, Inc. Mounds View, MN 55112	Approval for the Attain Ability Straight Model 4396 Left Ventricular Lead. The Model 4396 lead is a 4 French, transvenous, steroid

			eluting, dual electrode, polyurethane insulated, single coil, straight tip, tine fixation lead intended for use in left heart coronary veins.
P080011/S004 **3/23/11** **180-Day**	Biofinity Contact Lenses	CooperVision, Inc. Pleasanton, CA 94588	Approval for an alternate labeling and packing site located at Cooper-Vision Inc., West Henrietta, New York.
P080014/S005 **3/29/11** **Real-Time**	CERVISTA HPV HR	Hologic, Inc. Marlborough, MA 01752	Approval for the increase of the volume of the HPV control in Cervista HPV HR test and labeling changes to the package insert.
P080015/S002 **3/29/11** **Real-Time**	CERVISTA HPV 16/18	Hologic, Inc. Marlborough, MA 01752	Approval for the increase of the volume of the HPV control in Cervista HPB 16/18 test and labeling changes to the package insert.
P080023/S006 **3/22/11** **180-Day**	ARCHITECT CORE	Abbott Laboratories Abbott Park, IL 60064	Approval for a manufacturing site located at Abbott Ireland Diagnostics Division in Sligo, Ireland.
P080029/S001 **3/11/11** **180-Day**	Quick-Close® Vascular Suturing System	Interventional Therapies, LLC North Attleboro, MA 02760	Approval for ergonomic changes to the Quick-Close® Vascular Suturing System.
P100010/S005 **3/24/11** **Real-Time**	Arctic Front® Cardiac CryoAblation Catheter	Medtronic CryoCath LP Quebec, Canada H9R 5Z8	Approval for a labeling change to extend the shelf-life of the device.

30-Day Notices (135 Day Supplement was not required)

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
N12159/S027 3/4/11	Surgicel Original, Surgicel Fibrillar and Surgicel NU-KNIT Absorbable Hemostats	Ethicon Incorporated Somerville, NJ 08876	Alternate cycle for the dehumidification oven.
N16895/S093 3/4/11	Bausch & Lomb SofLens (polymacon) Visibility Tinted Contact Lenses	Bausch & Lomb, Incorporated 3/4/11	Change to transfer raw material supplier processing from Sarasota, Florida to Germany.
P830061/S060 3/30/11	CapSure, Vitatron, Crystaline, Vitatron Excellence PS+	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P840001/S179 3/9/11	Restore Implantable Neurostimulators	Medtronic, Inc. Minneapolis, MN 55432	Implementation of an additional automated plating line at the plating supplier.
P840001/S180 3/9/11	Itrel®, Synergy® and Synergy Versitrel® IPGs, RestorePrime®, PrimeAdvanced®, Restore®, RestoreUltra® and RestoreAdvanced® INS	Medtronic, Inc. Minneapolis, MN 55432	Modification to epoxy dispense equipment parameters.
P840001/S181 3/17/11	Itrel 3 INS, Synergy Family INS, Pocket Adaptors	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of a new manufacturing mold and component supplier.
P850079/S049 3/16/11	Frequency XCEL Toric (Methafilcon a) Soft Contact Lens	CooperVision, Inc. Pleasanton, CA 94588	Change in location of the wet processing area and the use of an alternate biological indicator for sterilization release.
P850089/S073 3/30/11	Capsure, Z Novus, Vitatron, Excellence SS+, Impulse II	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P860004/S146	SynchroMed II	Medtronic, Inc.	Implementation of

3/9/11	Implantable Drug Pump	Minneapolis, MN 55432	an additional automated plating line at the plating supplier.
P860004/S148 3/22/11	SynchroMed II Infusion Pump	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of two new laser welding workstations and two new laser power supplies to the manufacturing process of the Implantable SynchroMed II Infusion Pump, Model 8637.
P860057/S076 3/3/11	Carpentier-Edwards PERIMOUNT® Pericardial Bioprostheses Heart Valve	Edwards Lifesciences, LLC Irvine, CA 92614	Addition of a new vessel for the Gluteraldehyde mixing process.
P870072/S047 3/10/11	Thoratec® Ventricular Assist Device (VAD) Surgical Implant Accessory Kit	Thoratec Corporation Pleasanton, CA 94588	Moving a manufacturing process in-house from a contract manufacturer.
P880047/S014 3/2/11	Gynecare Interceed Absorbable Adhesion Barrier	Ethicon, Inc. Somerville, NJ 08876	Change in the density limit for irradiation shippers.
P890003/S215 3/17/11	Prodigy IPG	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P890003/S216 3/30/11	CapSure, CapSure Model, Service Kit	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P890064/S025 3/29/11	*digene*® Hybrid Capture 2 (HC2) HPV DNA Test and *digene*® Hybrid Capture 2 (HC2) High Risk HPV DNA Test	QIAGEN Gaithersburg, Inc. Gaithersburg, MD 20878	Changes for *digene*® Hybrid Capture 2 (HC2) HPV DNA Test and *digene*® Hybrid Capture 2 (HC2) High Risk HPV DNA Test located in Gaithersburg, MD.
P900061/S099 3/30/11	Accessory – Upsizing Sleeve, Lead End Pin Cap	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P910007/S027	ARCHITECT Total	Abbott Laboratories	Change in the

3/7/11	PSA	Abbott Park, IL 60064	vendor of antifoam raw material for use in the ARCHITECT Total PSA.
P920015/S073 3/30/11	Sprint Quattro, Subcutaneous Lead, Transvene SVC Lead	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P930014/S047 3/9/11	AcrySof ReSTOR Intraocular Lenses and AcrySof IQ Toric Intraocular Lenses	Alcon Research, Ltd. Fort Worth, TX 76134	Implementation of a software modification to enhance and improve intraocular lens production.
P930039/S048 3/30/11	CapSure, SureFix, Vitatron Crystalline ActFix, Vitatron Pirouet S+	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P940015/S020 3/18/11	Synvisc® and Synvisc-One®	Genzyme Corporation Cambridge, MA 02142	Filling of an investigational drug on the INOVA filler machine, which is also used for filling the Synvisc® and Synvisc-One® products.
P950005/S032 3/3/11	Webster Electrophysiology Catheter, CELSIUS Ablation Catheter	Biosense Webster, Inc. Diamond Bar, CA 91765	Addition of a supplier for catheter tip electrodes.
P950008/S008 3/10/11	SILIKON 1000	Alcon Research Ltd. Fort Worth, TX 76134	Establish ISO classification for two controlled environment areas.
P950024/S028 3/30/11	CapSure Epicardial Pacing	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P950029/S057 3/3/11	REPLY SR/DR and ESPIRIT SR/DR Implantable Pacemakers	ELA Medical, Inc./ Sorin Group Plymouth, MN 55441	Removal of a hybrid baking step, and the addition of a hybrid cleaning step.
P960004/S048 3/24/11	THINLINE® II STEROX, FINELINE® II STEROX and FINELINE® II STEROX EZ	Boston Scientific Corporation St. Paul, MN 55112	Change from a scrub method of cleaning a lead body to a wipe method.

P960009/S109 3/9/11	Activa® Implantable Neurostimulators	Medtronic, Inc. Minneapolis, MN 55432	Implementation of an additional automated plating line at the plating supplier.
P960009/S110 3/9/11	Soletra®, Kinetra® Activa® PC and Activa® RC	Medtronic, Inc. Minneapolis, MN 55432	Modification to epoxy dispense equipment parameters.
P960009/S111 3/17/11	Activa SC INS, Soletra INS, Kinetrea INS, Pocket Adaptors	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of a new manufacturing mold and component supplier.
P960022/S008 3/28/11	SofLens66 and SofLens Toric (alphafilcon A) Soft Contact Lenses	Bausch & Lomb, Inc. Rochester, NY 14609	Change with the supplier of the raw material processing for the SofLens66 and SofLens Toric (alphafilcon A) Soft Contact Lenses.
P960042/S028 3/7/11	SLS II Spectranetics Laser Sheaths	Spectranetics Corporation Colorado Springs, CO 80921	Change the process for dispensing fluid adhesive from a manual method to a semi-automated method.
P970003/S122 3/2/11	VNS Therapy® System	Cyberonics, Inc. Houston, TX 77058	Addition of a cleaning step for the Printed Circuit Board.
P970003/S123 3/25/11	VNS Therapy® System	Cyberonics, Inc. Houston, TX 77058	Change to the pulse generator manufacturing process.
P970004/S105 3/9/11	InterStim® Implantable Neurostimulators	Medtronic, Inc. Minneapolis, MN 55432	Implementation of an additional automated plating line at the plating supplier.
P970004/S106 3/9/11	InterStim® and InterStim® II INS	Medtronic, Inc. Minneapolis, MN 55432	Modification to epoxy dispense equipment parameters.
P970004/S107 3/17/11	InterStim INS	Medtronic Neuromodulation Minneapolis, MN	Addition of a new manufacturing mold and component

		55432	supplier.
P970008/S055 3/2/11	Urologix Targis System for the Treatment of BPH	Urologix, Inc. Minneapolis, MN 55447	Removal of a tube trimming step and move the Control Unit keyboard assembly process in house.
P970012/S083 3/18/11	Kappa 400	Medtronic, Inc. Mounds View, MN 55112	New mold and an additional supplier for seal components.
P970013/S039 3/30/11	Microny Family of Pacemakers	St. Jude Medical – CRMD Sylmar, CA 91342	Alternate supplier for pace wires.
P970020/S061 3/18/11	Multi-Link Zeta RX Coronary Stent System	Abbott Vascular Temecula, CA 92591	Change in resin verification at receiving inspection.
P970037/S004 3/4/11	AutoDELFIA®/ DELFIA Xpress hAFP	PerkinElmer, Inc. Indianapolis, IN 46236	Change in the supplier of a raw material.
P970051/S067 3/2/11	Nucleus 24 Cochlear Implant System	Cochlear Americas Centennial, CO 80111	Changes to the manufacturing process for the use of new silicone injection molding equipment.
P980007/S018 3/7/11	ARCHITECT Free PSA	Abbott Laboratories Abbott Park, IL 60064	Change in the vendor of antifoam raw material for use in the ARCHITECT Free PSA assays.
P980016/S278 3/2/11	Secura DR/VR, Maximo II DR/VR, and Virtuoso II DR/VR ICDs	Medtronic, Inc. Mounds View, MN 55112	Change in supplier component testing.
P980016/S281 3/17/11	Secura DR/VR, Maximo II DR/VR, Virtuoso II DR/VR/V ICDs	Medtronic, Inc. Mounds View, MN 55112	Implementation of a new device manufacturing assembly line.
P980016/S282 3/24/11	Secura DR/VR, Maximo II DR/VR, Virtuoso II DR/VR ICDs	Medtronic, Inc. Mounds View, MN 55112	Addition of a dry plasma oxygen clean process step.
P980016/S283	Marquis, Maximo	Medtronic, Inc.	New mold and an

3/18/11		Mounds View, MN 55112	additional supplier for seal components.
P980016/S284 3/17/11	Secura DR/VR ICD, Virtuoso II DR/VR, Maximo II DR/VR, Entrust ICD, Virtuoso ICD	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P980016/S285 3/31/11	Maximo II, Secura, Virtuoso II ICDs	Medtronic, Inc. Mounds View, MN 55112	Addition of a new equipment controller for the print label files.
P980022/S095 3/30/11	Continuous Glucose Monitoring System, SOF-Sensor, Glucose Sensors	Medtronic MiniMed Northridge, CA 91325	Change to use a semi-automated tape application during sensor base assembly.
P980035/S203 3/3/11	Adapta, Relia, Sensia, Versa IPGs	Medtronic, Inc. Mounds View, MN 55112	Implementation of a new release of traceability software.
P980035/S204 3/24/11	Adapta, Versa, Sensia, Relia IPGs	Medtronic, Inc. Mounds View, MN 55112	Addition of a dry plasma oxygen clean process step.
P980035/S205 3/18/11	350 Series, Adapta, EnPulse, Kappa 600/650/700/800/ 900, Sigma	Medtronic, Inc. Mounds View, MN 55112	New mold and an additional supplier for seal components.
P980035/S206 3/17/11	Adapta/Versa/ Sensia IPG Family, Relia IPG and EnRhythm IPG	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P980035/S207 3/31/11	Adapta, Relia, Sensia, Versa IPGs	Medtronic, Inc. Mounds View, MN 55112	Addition of a new equipment controller for the print label files.
P980049/S063 3/31/11	Isoline 2CT and Isoline 2CR Leads	ELA Medical, Inc. Plymouth, MN 55441	Update to the current leads label printing software.
P980050/S058 3/30/11	Transvene CS/SVC	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P990001/S085 3/31/11	Vitatron DA+C, Vitatron DA+T Series IPGs	Medtronic, Inc. Mounds View, MN 55112	Addition of a new equipment controller for the print label files.

P990004/S021 3/2/11	Surgifoam Absorbable Gelatin Sponge, U.S.P.	Ethicon, Inc. Somerville, NJ 08876	Change in packaging line equipment.
P990009/S031 3/16/11	Floseal Hemostatic Matrix	Baxter Healthcare Corporation McGaw Park, IL 60085	Changes in the manufacturing methods or processes.
P990025/S027 3/3/11	NAVISTAR RMT Catheter	Biosense Webster, Inc. Diamond Bar, CA 91765	Addition of a supplier for catheter tip electrodes.
P000010/S020 3/22/11	AMPLICOR HCV Test, v.2.0/COBAS AMPLICOR HCV Test v2.0	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Discontinuation of Final Bulk Testing requirements for bulk Quantitation Standard (QS) and Internal Control (IC) reagents for 17 QS/IC products used with the associated assays.
P000012/S029 3/22/11	COBAS AmpliPrep /COBAS AMPLICOR HCV Test v2.0	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Discontinuation of Final Bulk Testing requirements for bulk Quantitation Standard (QS) and Internal Control (IC) reagents for 17 QS/IC products used with the associated assays.
P000014/S023 3/10/11	VITROS Immunodiagnostic Products Anti-HBs Reagent Pack and Calibrator	Ortho-Clinical Diagnostics Rochester, NY 14626	Change to manufacture and store the antifoam solution used in VITROS Anti-HBs Conjugate Reagent.
P000020/S014 3/17/11	Stinger, Stinger S, Stinger M, Stinger SM, Scorpion 2 and Scorpion 2M Ablation Catheters and Templink/ Templink M Extension Cables	C.R. Bard, Inc. Lowell, MA 01851	Addition of a new supplier for connector assemblies and plug cable connectors.
P010014/S030 3/24/11	Oxford Partial Knee System	Biomet, Inc. Warsaw, IN	Change to the heat sealing of blister

		46581	packs procedure by adding a new benchtop sealer.
P010015/S109 3/30/11	Attain	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P010019/S020 3/16/11	CIBA VISION (lotrafilcon B) Soft Contact Lenses	CIBA VISION Corporation Duluth, GA 30097	Change the endotoxin testing site to the CIBA VISION Johor Microbiology Laboratory in Johor, Malaysia.
P010023/S008 3/2/11	Maxum System	Ototronix, LLC St. Paul, MN 55110	Change to the IPC shell fabrication process.
P010030/S026 3/28/11	LifeVest Wearable Cardioverter	ZOLL Lifecor Corporation Pittsburgh, PA 15238	Addition of a new thermoforming machine.
P010031/S234 3/2/11	Concerto CRT-D, Maximo II CRT-D, and Concerto II ICD	Medtronic, Inc. Mounds View, MN 55112	Change in supplier component testing.
P010031/S236 3/17/11	Concerto, Concerto II ICD, Consulta CRT-D, Maximo II CRT-D	Medtronic, Inc. Mounds View, MN 55112	Implementation of a new device manufacturing assembly line.
P010031/S237 3/24/11	Concerto II ICD, Consulta, Maximo II CRT-Ds	Medtronic, Inc. Mounds View, MN 55112	Addition of a dry plasma oxygen clean process step.
P010031/S238 3/17/11	InSync Sentry CRT-D, Concerto ICD, Consulta CRT-D, Concerto II CRT-D, Maximo II CRT-D	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P010031/S239 3/31/11	Concerto II, Consulta, Maximo II CRT-Ds	Medtronic, Inc. Mounds View, MN 55112	Addition of a new equipment controller for the print label files.
P010068/S022 3/3/11	CELSIUS DS Ablation Catheter	Biosense Webster, Inc. Diamond Bar, CA 91765	Addition of a supplier for catheter tip electrodes.
P020004/S059 3/16/11	GORE EXCLUDER® AAA Endoprosthesis	W.L. Gore & Associates, Inc. Flagstaff, AZ	Removal of a cooling chamber and an update to

		86003	the touch screen software.
P020004/S060 3/18/11	GORE EXCLUDER® AAA Endoprosthesis	W.L. Gore & Associates, Inc. Flagstaff, AZ 86003	Automation of a trimming process.
P020030/S008 3/31/11	Stelix BR, Stelix II BRF, and Stelid II BTF/BJF Leads	ELA Medical, Inc. Plymouth, MN 55441	Update to the current leads label printing software.
P020047/S030 3/18/11	Multi-Link Vision and Multi-Link Mini Vision OTW and RX Coronary Stent System	Abbott Vascular Temecula, CA 92591	Change in resin verification at receiving inspection.
P020047/S031 3/18/11	Multi-Link Vision®, Multi-Link Mini Vision®, Multi-Link 8™, Multi-Link 8™ LL and Multi-Link 8™ SV Coronary Stent Systems	Abbott Vascular Temecula, CA 92591	Change in quality control testing for balloon rupture.
P030002/S023 3/29/11	Crystalens® Accomodating Intraocular Lens	Bausch & Lomb, Inc. Aliso Viejo, CA 92656	Relocation of the final inspection and pre-pack operation at the manufacturing facility located in Rancho Cucamonga, California.
P030017/S116 3/28/11	Precision® Spinal Cord Stimulator System	Boston Scientific Corporation Valencia, CA 91355	Addition of an alternate assembly method for the leads and extensions for the Precision® Spinal Cord Stimulator (SCS) System.
P030017/S117 3/30/11	Precision® Spinal Cord Stimulator (SCS) System	Boston Scientific Corporation Valencia, CA 91355	Addition of pouch sealing equipment for the in-house processing of products packaged in Tyvek pouches.
P030029/S012 3/14/11	ADVIA Centaur Anti-HBs Assay	Siemens Healthcare Diagnostics East Walpole, MA	Change of raw material used in the production of the

		02032	Lite Reagent buffer.
P030036/S026 3/30/11	SelectSecure	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P040012/S037 3/30/11	Acculink Carotid Stent System	Abbott Vascular, Inc. Santa Clara, CA 95054	Changes to the in-process inspection and specification for the Inner Member (IM) to hypotube bond of the device.
P040012/S038 3/30/11	Acculink Carotid Stent System	Abbott Vascular, Inc. Santa Clara, CA 95054	Addition of an alternate heat sealer.
P040016/S070 3/18/11	VeriFLEX (Liberté) Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Change in bacterial endotoxin test methodology.
P040020/S030 3/9/11	AcrySof ReSTOR and AcrySof IQ Toric Intraocular Lenses	Alcon Research, Ltd. Fort Worth, TX 76134	Implementation of a software modification to enhance and improve intraocular lens production.
P040038/S021 3/30/11	Xact® Carotid Stent System	Abbott Vascular, Inc. Santa Clara, CA 95054	Addition of an alternate heat sealer.
P040043/S038 3/16/11	GORE® TAG® Thoracic Endoprosthesis	W.L. Gore & Associates, Inc. Flagstaff, AZ 86003	Removal of a cooling chamber and an update to the touch screen software.
P040044/S036 3/10/11	Mynx® Vascular Closure Device	Access Closure, Inc. Mountain View, CA 94043	Addition of a supplier for subassemblies of the Mynx product family.
P050012/S036 3/2/11	DexCom Seven and Seven Plus Continuous Glucose Monitoring System	DexCom Inc. San Diego, CA 92121	Alternate Vendor and method of manufacture of the disposable seal component of the applicator assembly of the Seven and Seven Plus systems. The proposed

			change applies only to the disposable seal supplier and the method of manufacture; neither the materials nor the final design of the disposable seal are altered. Sensor performance and release specification will also remain unchanged.
P050020/S033 3/10/11	Freestyle Navigator Continuous Glucose Monitoring System	Abbott Diabetes Care, Inc. Alameda, CA 04502	Addition of an alternate supplier of the injection molded components of the Freestyle Navigator Continuous Glucose Monitoring System.
P050028/S016 3/22/11	COBAS TaqMan HBV Test for use with The High Pure System	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Discontinuation of Final Bulk Testing requirements for bulk Quantitation Standard (QS) and Internal Control (IC) reagents for 17 QS/IC products used with the associated assays.
P050034/S005 3/31/11	Implantable Miniature Telescope (IMT)	VisionCare Ophthalmic Technologies, Inc. Saratoga, CA 95070	Change to the biological indicator used in the sterilization process and to add an option for a second full cycle sterilization (double sterilization) to the manufacturing process if required.
P050051/S010 3/23/11	ARCHITECT AUSAB	Abbott Laboratories Abbott Park, IL 60064	Changes in two quality control test methods used for in-process testing of bulk components.

P060007/S008 3/30/11	ARCHITECT HBsAg and ARCHITECT HBsAg Confirmatory Assays	Abbott Laboratories Abbott Park, IL 60064	Specification change for the negative human plasma for the HBsAg assays.
P060007/S009 3/30/11	ARCHITECT HBsAg and ARCHITECT HBsAg Confirmatory Assays	Abbott Laboratories Abbott Park, IL 60064	Test method conversions for calf bovine serum for the two HBsAg assays.
P060007/S010 3/30/11	ARCHITECT HBsAg and ARCHITECT HBsAg Confirmatory Assays	Abbott Laboratories Abbott Park, IL 60064	Plasma test method conversions for ARCHITECT HBsAg and ARCHITECT HBsAg Confirmatory Assays.
P060007/S011 3/30/11	ARCHITECT HBsAg and ARCHITECT HBsAg Confirmatory Assays	Abbott Laboratories Abbott Park, IL 60064	Test method change for quantitating Anti-D and Anti-Y monoclonal antibodies which are used in the testing of the recombinant HBsAg subtype Ad (Code 98034) and HBsAg subtype Ay (Code 98035) antigens used in the ARCHITECT HBsAg and HBsAg Confirmatory assays.
P060011/S001 3/31/11	C-flex Intraocular Lens	Rayner Intraocular Lenses Limited East Sussex, England, U.K. BN37AN	Alternative optical measurement equipment.
P060027/S030 3/31/11	Situs OTW UW28D Lead	ELA Medical, Inc. Plymouth, MN 55441	Update to the current leads label printing software.
P060030/S017 3/22/11	COBAS AmpliPrep/ COBAS TaqMan HCV Test and COBAS TaqMan HCV Test for use with The	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Discontinuation of Final Bulk Testing requirements for bulk Quantitation Standard (QS) and

	High Pure System, v2.0		Internal Control (IC) reagents for 17 QS/IC products used with the associated assays.
P060039/S022 3/30/11	Attain StarFix	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P070007/S028 3/3/11	Talent Thoracic Stent Graft System	Medtronic Vascular Santa Rosa, CA 95403	Addition of a lubricant during assembly of the Captiva Delivery System.
P070007/S030 3/18/11	Talent Thoracic Stent Graft System with Captiva Delivery System	Medtronic Ireland Galway, Ireland	Transfer of post sterilization inspections to an alternate site.
P070015/S056 3/3/11	XIENCE V® Everolimus Eluting Coronary Stent System	Abbott Vascular Temecula, CA 92591	Change to the coating manufacturing process.
P070015/S059 3/18/11	XIENCE V® and PROMUS Everolimus Eluting Coronary Stent System	Abbott Vascular Temecula, CA 92591	Change in resin verification at receiving inspection.
P070022/S012 3/9/12	Adiana Permanent Contraception System	Hologic, Inc. Marlborough, MA 01752	Addition of a manufacturing step for the Adiana matrix component.
P080006/S020 3/30/11	Attain Ability	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P090003/S009 3/9/11	Express™ LD Iliac Premounted Stent System	Boston Scientific Maple Grove, MN 55311	Modification in the balloon wingfolding operation during manufacture of the device.
P090003/S010 3/18/11	Express LD Iliac Premounted Stent Systems	Boston Scientific Corporation Maple Grove, MN 55311	Change in bacterial endotoxin test methodology.
P090006/S005 3/18/11	Complete SE Vascular Stent System	Medtronic Ireland Galway, Ireland	Transfer of post sterilization inspections to an alternate site.
P090013/S001	REVO MRI™	Medtronic, Inc.	Multiple changes in

3/18/11	SureScan® Pacing System	Mounds View, MN 55112	suppliers of various electronic components.
P090013/S002 3/17/11	REVO MRI™ SureScan® Pacing System	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P090013/S003 3/25/11	REVO MRI™ SureScan® Pacing System	Medtronic, Inc. Mounds View, MN 55112	Upgrades to various manufacturing process software versions.
P090013/S004 3/30/11	CapSure Fix	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P090013/S005 3/28/11	REVO MRI™ SureScan® Pacing System	Medtronic, Inc. Mounds View, MN 55112	Changes to align production with existing processes used in other marketed devices.
P090013/S007 3/31/11	Revo MRI™ SureScan® Pacing System	Medtronic, Inc. Mounds View, MN 55112	Revising parameters to an epoxy dispense manufacturing process.
P090013/S008 3/31/11	Revo MRI IPG	Medtronic, Inc. Mounds View, MN 55112	Addition of a new equipment controller for the print label files.
P100010/S003 3/9/11	Arctic Front Cardiac CryoAblation Catheter	Medtronic Cryocath LP Quebec, Canada H9R 5ZB	Change of the adhesive used to seal the vacuum tube to rear strain.
P100021/S005 3/16/11	Endurant® Stent Graft System	Medtronic Vascular Santa Rosa, CA 95403	Addition of an automated crimping machine used during the radiopaque marker-band bond process of the Endurant Delivery System.
P100021/S006 3/18/11	Endurant® Stent Graft System	Medtronic Ireland Galway, Ireland	Transfer of post sterilization inspections to an alternate site.
P100021/S007 3/18/11	Endurant® Stent Graft System	Medtronic Ireland Galway, Ireland	Improvements upon the current process for stent graft

			loading.

Summary of PMA Originals & Supplements Approved
Originals: 2
Supplements: 89

Summary of PMA Originals Under Review
Total Under Review: 96
Total Active: 47
Total On Hold: 49
Number Greater Than 180 Days: 4

Summary of PMA Supplements Under Review
Total Under Review: 654
Total Active: 457
Total On Hold: 197
Number Greater Than 180 Days: 11

Summary of All PMA Submissions Received
Originals: 3
Supplements: 97

Summary of PMA Supplement PMA Approval/Denial Decision Times
Number of Approvals: 89
Number of Denials: 0
Average Days Fr Receipt to Decision (Total Time): 210.8
FDA Time: 122.4 Days MFR Time: 88.4 Days

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